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09/938,628	08/27/2001	Patrick G. Morand	06478.1459-00000	1173

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02/05/2007

EXAMINER

KOPPIKAR, VIVEK D

ART UNIT	PAPER NUMBER
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3626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/938,628

Applicant(s)

MORAND ET AL.

Examiner

Vivek D. Koppikar

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Claims 24-68 have been examined in this application. This communication is the first action on the merits since the applicants filed a Request for Continued Examination (RCE) on December 1, 2006.

Claim Objections

2. Claim 49 is objected to because of the following informalities: It is not clear what the applicants mean by the phrase "donor from at least one collection establishment". Appropriate correction and/or clarification is required. For the purposes of examination, this phrase will be interpreted to mean the place at which the donor's biological sample is collected from.

In claim 49 it is also not clear what the applicants mean when they state that the steps b to d may be performed in any order. It is not clear to the examiner how the step of deriving proteomic information and genomic information from the sample can be performed before a sample is collected from the donor. Appropriate correction and/or clarification is required. For the purposes of examination, the examiner will interpret these steps (steps b through d) as being performed in the same order as they are recited in claim 49.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3626

4. Claims 24, 28-30, 33-36, 38, 42-44 and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,991,729 in view of US Patent Number 6,368,797 to Schappert and in further view of “Avandel Healthcare Selects ThinkMed to Support Early Identification and Medical Management of Patients with Catastrophic Diseases” (hereinafter referred to as Avandel).

(A) As per claim 24, the combined teachings of Barry in view of Schappert in view of Avandel teach a method for identifying a research subject in a group of donors from at least one collection establishment, comprising:

- a. obtaining a biological sample and medical data from a donor (Barry: Col. 4, Ln. 9-12);
- b. associating an identifier for said donor with said biological sample and medical data in at least a first database (Barry: Col. 4, Ln. 32-48).
- c. associating the identifier for said blood donor with the name and contact information of said donor (Barry: Col. 4, Ln. 32-48)
- f. matching the identifier from the first database with the name and contact information (Col. 4, Ln. 32-48).

Barry does not teach the step d. of identifying criteria for selecting a research subject nor does Barry teach the step e. of extracting an identifier from the first database, wherein said identifier is associated with a donor matching the identified criteria; however, this feature is well known in the art as evidenced by Schappert (Col. 12, Ln. 43-52). At the time of the invention it would have been obvious to one of ordinary skill in the art to have modified the method in Barry with the aforementioned feature from

Art Unit: 3626

Schappert with the motivation of providing a powerful prognostic tool for the treatment of a disease as recited in Schappert (Col. 12, Ln. 27-33).

The combined teachings of Barry and Schappert do not teach that the purpose of the matching step (step (f)) is in order to identify a research subject nor do they teach certain criteria for a research project, however, this feature is well known in the health care industry as illustrated by Avandel, which teaches a means of identifying potentially high-risk and high-cost patients (e.g. certain criteria) from querying medical data in a database (Avandel: Paragraphs 5-6). These high-risk and high-cost patients are then recommended for management interventions (e.g. clinical or research trials). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the teachings of Barry in view of Schappert with the aforementioned teachings from Avandel with the motivation of having a means to better plan and implement management strategies in a health maintenance organization, as recited in Avandel (Paragraph 6).

(B) As per claim 28, in the combined method of Barry in view of Schappert in view of Avandel the medical data comprises medical history data (Barry: Col. 4, Ln. 26-48).

(C) As per claim 29, in the combined method of Barry in view of Schappert in view of Avandel the medical data comprise a family history (Barry: Col. 4, Ln. 26-48).

(D) As per claim 30, in the combined method of Barry in view of Schappert in view of Avandel the medical data comprise clinical test results (Barry: Col. 4, Ln. 7-12).

(E) As per claim 33, in the combined method of Barry in view of Schappert in view of Avandel the criteria include medical history information (Barry: Col. 4, Ln. 26-48).

Art Unit: 3626

(F) As per claim 34, in the combined method of Barry in view of Schappert in view of Avandel the criteria include family history information (Barry: Col. 4, Ln. 26-48).

(G) As per claim 35, in the combined method of Barry in view of Schappert in view of Avandel the criteria include clinical test results (Barry: Col. 4, Ln. 9-12).

(H) As per claim 36, in the combined method of Barry in view of Schappert in view of Avandel the criteria include pharmacogenomic or genomic information (Barry: Col. 4, Ln. 7-24).

(I) As per claim 38, in the combined method of Barry in view of Schappert in view of Avandel the first database is a computerized database (Barry: Col. 4, Ln. 26-29 and Ln. 48-52).

(J) As per claims 42-44, in the combined method of Barry in view of Schappert in view of Avandel the database is computerized, and the network is either an intranet or the Internet (Barry: Col. 4, Ln. 56-Col. 5, Ln. 6).

(K) As per claim 66, the combined method of Barry in view of Schappert in view of Avandel teaches the step of identifying the research subject according to claim 1 according to the selected criteria (Schappert: Col. 12, Ln. 43-52); and also teaches the step of contacting the research subject for recruiting the research subject for a clinical study (Barry: Col. 4, Ln. 26-47). The motivation for combining these two teaching is stated above in the paragraph setting forth the rejection of Claim 1.

(L) As per claim 67, the combined method of Barry in view of Schappert in view of Avandel teaches the step of identifying the research subject according to claim 1 according to the selected criteria (Schappert: Col. 12, Ln. 43-52); and also teaches the step of contacting the research subject for recruiting the research subject for a clinical

Art Unit: 3626

study (Barry: Col. 4, Ln. 26-47). The motivation for combining these two teaching is stated above in the paragraph setting forth the rejection of Claim 24.

5. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Schappert as applied to Claims 1 and 24, above, respectively.

(A) As per claim 25, the combined method of Barry in view of Schappert in view of Avandel does not teach the step of obtaining informed consent from the subject, wherein the informed consent permits the medical data to be used to identify the subject as a potential research subject, however, the examiner takes Official Notice that this feature is well known in the field of patient and medical records. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have obtained informed consent from a patient before using that patient's medical records with the motivation of protecting the patient's right to privacy.

6. Claim 48 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of US Patent Application Publication 2002/0035486 to Huyn.

(A) As per claim 48, Barry teaches a plurality of biological samples collected from at least one donor (Barry: Abstract), wherein each sample is collected at a collection establishment and associated with an identifier linking the donor and the biological sample to at least one of medical data, genomic data, pharmacogenomic data, and proteomic data in at least a first database (Barry: Col. 4, Ln. 7-47). Barry does not teach that the biological samples are collected and stored longitudinally; however, this feature is well known in the art as evidenced by Huyn (Section [0088]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the invention of Barry with the aforementioned feature from Huyn with the motivation of

Art Unit: 3626

having a means of collecting data at either regular or irregular time intervals, as recited in Huyn (Section [0088]).

(B) As per claim 47, in the combined invention of Barry in view of Tacklind the samples are blood and blood cells (Barry: Col. 4, Ln. 7-12).

7. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Huyn.

(A) As per claim 49, Barry teaches a method for creating a database (Barry: Abstract), the method comprising:

- a. collecting a biological sample from at least one donor from at least one collection establishment (Barry: Col. 4, Ln. 7-12);
- b. collecting medical data from at least one subject (Barry: Col. 4, Ln. 7-12);
- c. deriving proteomic information and genomic information from the sample (Barry: Col. 4, Ln. 22-26);
- d. storing the sample in a location from which the sample can be recovered (Barry: Col. 4, Ln. 21-26);
- e. associating the medical data, the proteomic information, and the genomic information with an identifier that can be used to locate the sample (Barry: Col. 4, Ln. 33-47).

Barry does not teach or suggest the step of f. of performing steps a to e on the same subject longitudinally and also does not suggest that these steps b to d are be performed in any order; however, this feature is well known in the art as evidenced by Huyn (Section [0088]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the invention of Barry with the

Art Unit: 3626

aforementioned feature from Huyn with the motivation of having a means of collecting data at either regular or irregular time intervals, as recited in Huyn (Section [0088]).

(B) As per claim 50, in the combined method of Barry in view of Tacklind the steps a to f are performed on multiple donors (patients) (Barry: Col. 5, Ln. 28-47).

(C) As per claim 51, in the combined method of Barry in view of Tacklind the biological sample is blood (Barry: Col. 4, Ln. 7-12).

(E) As per claim 53, in the combined method of Barry in view of Tacklind the medical data comprises chemistry test formation (Barry: Col. 4, Ln. 16-26).

(F) As per claim 59, in the combined method of Barry in view of Tacklind the medical data comprises family histories from the subjects (Barry: Col. 4, Ln. 33-47).

(G) As per claim 60, in the combined method of Barry in view of Tacklind the medical data comprises demographic information from the subjects (Barry: Col. 4, Ln. 33-47).

(H) As per claim 61, in the combined method of Barry in view of Tacklind the medical data comprises at least one of the medical data, the genomic information, the proteomic information, and the location for the sample is associated with an identifier for the subject that can be used to retrieve the name and contact information for the subject (Barry: Col. 5, Ln. 19-27).

8. Claims 27 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Schappert as applied to Claims 1 and 24, above, respectively, and in further view of US Patent Number 5,915,240 to Karpf.

(A) As per claims 27 and 68, the combined method of Barry in view of Schappert does not teach or suggest that the subject (patient) is a deferred donor, however, this

Art Unit: 3626

feature is well known in the art as evidenced by Karpf (Col. 14, Ln. 27-34). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the combined method of Barry in view of Schappert with the aforementioned feature from Karpf with the motivation of providing a means to providing descriptions of the patient, as recited in Karpf (Col. 14, Ln. 31-33).

9. Claims 31-32, and 36-37 are rejected as being unpatentable over Barry in view of Schappert as applied to Claims 1 and 24, above, respectively, and in further view of US Patent Number 6,730,477 to Sun.

(A) As per claims 31-32, and 36-37 the combined method of Barry in view of Schappert does not teach that the medical data comprises pharmacogenomic, genomic or proteomic data, however, this feature is well known in the art as evidenced by Sun (Col. 6, Ln. 61-Col. 7, Ln. 8 and Col. 7, Ln. 10-23 and Col. 8, Ln. 31-49). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have included these types of medical data in the combined method of Barry in view of Schappert with the motivation of obtaining an enhanced means of detecting, diagnosing and monitoring various diseases, as recited in Sun (Col. 3, Ln. 63-Col. 4, Ln. 4).

10. Claims 55-58 and 62-65 are rejected as being unpatentable over Barry in view of Tacklind, as applied to Claim 49, above and in further view of Sun.

(A) As per claims 55-58 and 62-65, the combined method of Barry in view of Tacklind does not teach that the medical data comprises pharmacogenomic, genomic or proteomic data as well as the other recited types of data in these claims, however, this feature is well known in the art as evidenced by Sun (Col. 6, Ln. 61-Col. 7, Ln. 8 and Col. 7, Ln. 10-23 and Col. 8, Ln. 31-49). At the time of the invention, it would have been

Art Unit: 3626

obvious to one of ordinary skill in the art to have included these types of medical data in the combined method of Barry in view of Schappert with the motivation of obtaining an enhanced means of detecting, diagnosing and monitoring various diseases, as recited in Sun (Col. 3, Ln. 63-Col. 4, Ln. 4).

11. Claims 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Schappert, as applied to Claims 1 and 24, above, respectively.

(A) As per claims 39-42, the combined method of Barry in view of Schappert does not teach or suggest a second computerized database stored on a separate computer and a network firewall separating the first and second computers, however, the examiner take Official Notice that this is a feature well known in the field of informational technology and computer networks. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included the above mentioned features with the motivation of providing a backup, archival data source so that vital patient data would not be destroyed if one of the computers was damaged.

Response to Arguments

12. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new grounds of rejection.

In addition, in response to applicant's arguments that the previously used prior art references teach methods that are not used for identifying research subjects from a database of biological samples or patient medical data, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior

Art Unit: 3626

art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

13. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.


If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,


Vivek Koppikar

1/23/2007


Patent Examiner -3626
2/2/07